K123544
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510(k) Summary

RapidCross™ PTA Rapid Exchange Balloon Dilatation Catheter

FEB 1 2 2013

510(k) Summary	This 510(k) summary information is submitted in accordance with the requirements of 21 C.F.R §807.92.
Applicant	ev3 Inc.
Submitter	ev3 Inc. 3033 Campus Drive Plymouth, MN 55441-2651 Tel: 763-398-7000 Fax: 763-591-3248
Contact Person	Laura J. Lind
Date Prepared	February 6, 2013
Device Trade Name	RapidCross™ PTA Rapid Exchange Balloon Dilatation Catheter
Device Common Name	PTA Dilatation Catheter
Classification Name	Catheter, Angioplasty, Peripheral, Transluminal (21 CFR 870.1250, Product Codes LIT, DQY)
Classification Panel	Cardiovascular
Predicate Devices	NanoCross™ .014 OTW PTA Dilatation Catheter (K082854, K090849), PowerCross™ .018 OTW PTA Dilatation Catheter (K093286), Sterling™ Monorail™ PTA Balloon Dilatation Catheter (K053118), and Advance® 14LP Low Profile PTA Balloon Dilatation Catheters (K090822).
Intended use	The RapidCross™ PTA Rapid Exchange Balloon Dilatation Catheter is intended to dilate stenosis in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
Device Description	The RapidCross PTA Rapid Exchange Balloon Dilatation Catheter (RapidCross catheter) is a rapid exchange (RX) coaxial catheter compatible with 0.014" guidewires, with a distally mounted semi-compliant inflatable balloon and an atraumatic, tapered tip. The distal portion of the catheter has a lubricious coating. The manifold includes an inflation lumen, which is used to inflate and deflate the dilatation balloon with a mixture of

contrast medium and saline solution. The balloon has two radiopaque markers for positioning the balloon relative to the stenosis. The radiopaque marker bands indicate the dilating or working section of the balloon. On the 150 mm and 210 mm devices, two additional marker bands denote the middle of the balloon body. A guidewire lumen starts at a guidewire port located 35 cm from the catheter tip and extends to the distal tip. The 90 cm useable length devices have proximal depth marks printed on the proximal shaft at lengths of 55 cm and 65 cm from the distal tip while the 170 cm useable length devices have depth marks at 90 cm and 100 cm to serve as a reference during catheter insertion.

The RapidCross catheter is available in balloon sizes ranging from 2 mm to 4 mm in diameter and 20 mm to 210 mm in length; and, all sizes are compatible with 4 F sheaths.

Performance data

Bench testing and biocompatibility testing were performed to support a determination of substantial equivalence. Results from this testing provide assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use.

Using internal Risk Analysis procedures, the following tests were performed:

• Crossing Profile	• Radiopacity
• Balloon Burst Strength	• Presence of Coating
• Balloon Compliance	• Coating Durability
• Balloon OD	• Particle Generation
• Inflation/Deflation Time	• Pushability
• Balloon Fatigue	• Support Wire Securement
• Bond Tensile Strength	• Tip ID / RX Port ID
• Kink	• Tip / Lesion Entry Profile
• Device Tracking	• Re-Insertion Force
• Insertion Force	• Catheter Working Length
• Balloon Pull-back Force	• RX Port Length
• Repeat Inflations (In Stent)	• RX Port OD
• Torque Strength	

The device was tested for biocompatibility per ISO 10993-1 for short duration contact with blood (<24 hours). The testing included cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, hemolysis, pyrogen, complement activation, thromboresistance, partial thromboplastin time, and platelet/leukocyte count.

The RapidCross catheter met all acceptance criteria for the

	bench testing with results similar to the predicates. Based on the bench test results, comparison to legally marketed predicates, and non-clinical test results, the RapidCross catheter is determined to perform as safely and effectively as the predicates for its intended use.
Summary of Substantial Equivalence	The RapidCross PTA Rapid Exchange Balloon Dilatation Catheter has the following similarities to the predicate devices: • Same intended use (all predicates) • Same indications for use (NanoCross PTA Dilatation Catheter) • Similar fundamental scientific technology (all predicates) • Similar operating principle (all predicates) • Similar technological characteristics • Same sterility assurance level and sterilization method (NanoCross) All devices are compatible with 0.014" wires and 4F sheaths. All devices have similar construction and principles of operation. All devices are used by the physician in a similar manner typical of PTA balloon catheters. The RapidCross catheter and the predicates have the same intended use - all devices are intended to treat peripheral arteries. All devices are intended to treat the same target population. The manner in accessing and treating lesions is similar for the devices. The RapidCross catheter indications for use are the same as the ev3 NanoCross PTA Dilation Catheter indications for use. The minimal differences between RapidCross and indications for use of the other predicates do not raise new safety and effectiveness questions.
Conclusion	Based on the intended use, technological characteristics, and results from safety and performance testing, the RapidCross PTA Rapid Exchange Balloon Dilatation Catheter is considered substantially equivalent to the legally marketed predicate devices NanoCross .014 OTW PTA Balloon Dilatation Catheter (K082854, K090849), PowerCross PTA Dilatation Catheter (K093286) Sterling Monorail PTA Balloon Dilatation Catheter (K053118), and Advanced LP Dilatation Catheter (K090822).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

ev3 Inc.
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

FEB 1 2 2013

Re: K123544
Trade/Device Name: RapidCross PTA Rapid Exchange Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT, DQY
Dated: January 23, 2013
Received: January 24, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K123544

Device Name: RapidCross™ PTA Rapid Exchange Balloon Dilatation Catheter

Indications for Use:

The RapidCross™ PTA Rapid Exchange Balloon Dilatation Catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K123544